

Claims

1. Method for treating or preventing a respiratory disease in a patient, which patient is a child and the method comprising administering to the patient a dose of a composition containing ciclesonide, a pharmaceutically acceptable salt, solvates or physiologically functional derivative thereof, wherein the dose of the composition comprises ciclesonide in an amount of from 20 to 200 µg.
2. Method according to claim 1, wherein the dose comprises 20, 40, 60, 80, 100, 120, 140, 160, 180 or 200 µg ciclesonide.
3. Method according to claim 1, wherein the dose comprises 40, 80 or 160 µg ciclesonide.
4. Method according to claim 1, wherein the child is a pre-pubertal human.
5. Method according to claim 1, wherein the child is a human from 6 to 12 years of age.
6. Method according to claim 1, wherein the dose is a daily dose in a continuous treatment regimen.
7. Method according to claim 6, wherein the treatment period is more than one day.
8. Method according to claim 7, wherein the treatment period is more than one week.
9. Method according to claim 1, which has no effect on growth rate of the patient.
10. Method according to claim 1, wherein the composition comprises a pharmaceutically acceptable carrier and/or one or more excipients.
11. Method according to claim 1 wherein ciclesonide is selected from the group of [11β,16α(R)]-16,17-[(Cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, [11β,16α(S)]-16,17-[(Cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, [11β,16α(R,S)]-16,17-[(Cyclohexyl-methylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, 16α,17-(22R)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion, 16α,17-(22S)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion and 16α,17-(22R,S)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion.

12. Method according to claim 1, comprising a once daily dosage regimen.
13. Method according to claim, wherein the composition is suitable for administration by inhalation.
14. Method according to claim 13 wherein the composition is a pharmaceutical aerosol formulation comprising a therapeutically effective amount of ciclesonide and a hydrofluorocarbon propellant, preferably selected from 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and cosolvent in an amount effective to solubilize ciclesonide and optionally a surfactant.
15. Method according to claim 14, wherein the cosolvent is ethanol.
16. Method according to claim 13 wherein the composition is a pharmaceutical aerosol formulation comprising particles of ciclesonide in a therapeutically effective amount and a hydrofluorocarbon propellant, preferably selected from 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and 0.01 to 5 % w/w based upon propellant of polar cosolvent and optionally a surfactant.
17. Method according to claim 13 wherein the composition is a dry powder and the carrier is a saccharide
18. Method according to claim 13 wherein the carrier is lactose monohydrate.
19. Method according to claim 1, wherein the clinical condition is selected from the group of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic and wheezy bronchitis, emphysema, respiratory tract infection and upper respiratory tract disease, rhinitis, allergic and seasonal rhinitis.
20. Method according to claim 1, wherein the clinical condition is mild or moderate asthma.
21. Method according to claim 1, wherein the ciclesonide essentially consists of R epimer.
22. Use of ciclesonide, a pharmaceutically acceptable salt, solvates or physiologically functional derivative thereof for the manufacture of a medicament for the treatment or prevention of a respiratory disease in a patient, which patient is a child and wherein the medicament is administered at a dose of 20 to 200 µg ciclesonide.

23. Use according to claim 22, wherein the child is a pre-pubertal human.
24. Use according to claim 22, wherein the child is a human from 6 to 12 years of age.
25. Use according to claim 22, wherein the medicament is administered at a dose of 20, 40, 60, 80, 100, 120, 140, 160, 180 or 200 µg ciclesonide.
26. Use according to claim 22, wherein the medicament is administered at a dose of 40, 80, 160µg ciclesonide.
27. Use according to claim 22, wherein the dose is a daily dose in a continuous treatment regimen.
28. Use according to 27, wherein the treatment period is more than one day.
29. Use according to claim 28, wherein the treatment period is more than one week.
30. Use according to claim 22, which has no effect on growth rate of the patient.
31. Use according to claim 22, wherein the medicament comprises a pharmaceutically acceptable carrier and/or one or more excipients.
32. Use according to claim 22, wherein ciclesonide is selected from the group of [11β,16α(R)]-16,17-[(Cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, [11β,16α(S)]-16,17-[(Cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, [11β,16α(R,S)]-16,17-[(Cyclohexyl-methylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, 16α,17-(22R)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion, 16α,17-(22S)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion and 16α,17-(22R,S)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1,4-dien-3,20-dion.
33. Use according to claim 22, comprising a once daily dosage regimen.
34. Use according to claim 22, wherein the medicament is suitable for administration by inhalation.
35. Use according to claim 34, wherein the composition is a pharmaceutical aerosol formulation comprising a therapeutically effective amount of ciclesonide and a hydrofluorocarbon propellant,

preferably selected from 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and cosolvent in an amount effective to solubilize ciclesonide and optionally a surfactant.

36. Use according to claim 35, wherein the cosolvent is ethanol.
37. Use according to claim 34, wherein the composition is a pharmaceutical aerosol formulation comprising particles of ciclesonide in a therapeutically effective amount and a hydrofluorocarbon propellant, preferably selected from 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and 0.01 to 5 % w/w based upon propellant of polar cosolvent and optionally a surfactant.
38. Use according to claim 34, wherein the composition is a dry powder and the carrier is a saccharide
39. Use according to claim 34, wherein the carrier is lactose monohydrate.
40. Use according to claim 22, wherein the respiratory disease is selected from the group of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic and wheezy bronchitis, emphysema, respiratory tract infection and upper respiratory tract disease, rhinitis, allergic and seasonal rhinitis.
41. Use according to claim 22, wherein the respiratory disease is mild or moderate asthma.
42. Use according to claim 22, wherein the ciclesonide essentially consists of *R* epimer.